UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:15-cv-3278-RA-RLE

MEMORANDUM IN SUPPORT OF
TAKEDA'S MOTION TO DISMISS COUNT 1

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INTRODUCTION

In *In re Actos End Payor Antitrust Litigation*, No. 13-cv-9244, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015) ("*End Payor*"), the plaintiffs alleged that Takeda had described two of its patents (the '584 and '404 patents) to the FDA as containing "product" claims, that this description was improper, that this description caused generic applicants file paragraph IV certifications rather than seek FDA permission to use section viii carve-outs, and that there would have been earlier sale of generic ACTOS had Takeda described these two patents only as "method" patents. The Court dismissed these antitrust claims, holding that the plaintiffs "ha[d] not plausibly alleged an antitrust injury resulting from Takeda's conduct." *Id.* at *21.

Plaintiffs are now making precisely the same claim. Putting aside rhetoric and argumentative language, the factual allegations in the current Amended Complaint regarding Takeda's Orange Book listing are the same as in *End Payor*. Despite having the benefit of all the briefing and the Court's decision in *End Payor*, the Amended Complaint here does not and cannot remedy any of the fatal flaws in this claim. Plaintiffs' theory does not make sense at any level.

First, Takeda was required to list the '584 and '404 patents in the Orange Book for ACTOS, and it was perfectly appropriate, factually accurate, and even necessary that Takeda identified those patents as including "product" claims as well as method-of-use claims. In the ACTOS patent litigation, Judge Cote specifically held that the product claims in these patents could reasonably be asserted against generic versions of ACTOS, and "reasonable" assertion is the standard for requiring patents to be submitted to the FDA.

Second, as it happens, the Orange Book in fact has never listed these patents as having product claims. Due to the listing approach the FDA followed at the time, Takeda's submission of the patents as having product claims was not made public for a decade. Thus, the generic

applicants filed paragraph IV certifications even though the Orange Book specified the patents only had method-of-use claims. It was not Takeda's supposedly improper description of its patents that caused those certifications. The certifications were filed because Hatch-Waxman requires listing of and certification for an *entire* patent and all its claims, not some subset of its claims. Regardless of how Takeda described its patents to the FDA, no precedent allows generic applicants to ignore claims in a patent listed in the Orange Book. Nothing Takeda did changed the fact that the generics submitted, and had to submit, paragraph IV certifications for the patents.

Third, Plaintiffs ignore the fact that section viii labeling carve-outs for patented methods require FDA approval. A carve-out is improper if, for example, the carve-out would render the proposed generic drug less safe or effective than the pioneer. Plaintiffs do not allege facts suggesting how the FDA would have decided requests for labeling carve-outs for generic versions of ACTOS. Nor can Plaintiffs base an antitrust claim on predicting how the FDA would decide such a complex question.

Fourth, Plaintiffs do not plausibly allege a mechanism by which Takeda's conduct actually delayed any generic approval the FDA was otherwise poised to grant. They do not, for example, allege that any proposed generic label actually carved out Takeda's patented methods of use as specified in the Orange Book. And they are unable to identify any specific generic applicant that would have received earlier approval but for the supposedly improper conduct.

Fifth, regardless of how Takeda described its patents, Takeda was able to bring—and in fact brought—lawsuits against ANDA filers for infringement of the patents. Plaintiffs do not allege facts that demonstrate that the generic companies could have or would have launched their products at risk and exposed themselves to potentially catastrophic treble damages for willful

patent infringement.

Sixth, no court ever found Takeda's patents invalid or not infringed. Plaintiffs are not entitled to claim as antitrust injury the inability to purchase products that might infringe valid patents. Nor can they base their antitrust claims on speculation that Takeda would not have prevailed on its claims for infringement.

Finally, Plaintiffs have failed to plausibly allege bad faith on Takeda's part in describing the patents to the FDA. Treble-damage antitrust liability cannot be imposed based on reasonable, good-faith efforts to comply with complex regulatory requirements.

Each of these fundamental problems with Plaintiffs' claim is independently sufficient to require dismissal. Count 1 should thus be dismissed with prejudice given the long list of fatal flaws in Plaintiffs' claim.

BACKGROUND

The facts relevant to Plaintiffs' "improper Orange Book description" claim are summarized below. The applicable Hatch-Waxman rules for listing patents covering new drugs and the resolution of related patent disputes are described in the Court's prior opinion and are not repeated here. *See End Payor*, 2015 WL 5610752, at *1-3.

I. Development of ACTOS and Related Patents

In the mid-1980s, after decades of work, scientists at Takeda in collaboration with scientists at Upjohn synthesized pioglitazone and discovered that it was an effective, low-toxicity treatment for type 2 diabetes. *See Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341, 344-64 (S.D.N.Y. 2006) (describing the invention of pioglitazone). Takeda applied for and received U.S. Patent No. 4,687,777 covering pioglitazone. The '777 patent has never been held invalid but was rather upheld by Judge Cote and the Federal Circuit. *See id.* at 399; *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). Plaintiffs do not

dispute that generic ACTOS could not have been legally marketed before the '777 patent expired in 2011. *See* Dkt. 55, Second Consolidated Complaint ("Am. Compl.") ¶ 13.

In the mid-1990s, Takeda's scientists unexpectedly discovered that when patients took pioglitazone in combination with other anti-diabetic therapies, the combinations provided enhanced glycemic control with smaller doses and with reduced side effects. Takeda applied for patents on several of these "combination therapies."

Takeda received U.S. Patent No. 5,965,584, which claims pharmaceutical compositions comprising pioglitazone and metformin (and other biguanides), as well as methods of treating a patient with that combination. Ex. 6, '584 patent at 18:19-21, 18:65-67 (claims 4 and 10). Takeda received U.S. Patent No. 6,329,404, which claims pharmaceutical compositions comprising pioglitazone and sulfonylureas or other insulin secretion enhancers, as well as methods of treating patients with that combination. Ex. 7, '404 patent at 18:7-9, 18:64-65 (claims 2 and 14); *see also id.* at 12:44-45 (including "sulfonylureas"). Takeda also received numerous other patents covering methods of using pioglitazone in combination with various other anti-diabetic therapies, patents that the Amended Complaint refers to as the "Method-of-Use Patents." *See* Am. Compl. ¶ 178. The '584, '404, and method-of-use patents expire in 2016. *See id.* ¶¶ 166, 172, 178.

Importantly, the '584 and '404 patents are not limited to fixed-dose combinations in a single pill. Both patents cover the administration of pioglitazone and either metformin or sulfonylureas to a patient separately. The patents are explicit about this. The '584 patent explains, for example, that pioglitazone and metformin "can be administered independently of each other, either concurrently or at staggered times to the same subject." Ex. 6, '584 patent at 13:32-36; *see also* Ex. 7, '404 patent at 13:30-34 (same for pioglitazone and sulfonylurea).

Thus, a company selling a pioglitazone-only pill can still be liable for induced infringement of the method-of-use and composition claims of the '584 and '404 patents because a pioglitazone pill can be administered with metformin or sulfonylureas. *See, e.g.*, *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988). In one of the ACTOS patent cases, Judge Cote specifically held that Takeda could assert a claim of induced infringement of these combination-use patents even if the generics sold only a pioglitazone pill. *End Payor*, 2015 WL 5610752, at *23 (quoting *Takeda Pharms. Co. v. Sandoz, Inc.*, 2007 WL 2936208, at *5 (S.D.N.Y. Oct. 9, 2007) (rejecting the argument "that a generic drug manufacturer cannot induce infringement of combination-use patents")).

II. Takeda's New Drug Application for ACTOS

In 1999, the FDA approved Takeda's NDA for pioglitazone. Am. Compl. ¶ 160. Takeda launched the drug in the United States under the brand name ACTOS, which "has been a hugely successful commercial product." *Takeda*, 417 F. Supp. 2d at 347. As mandated by the Hatch-Waxman Act, Takeda submitted all of its pioglitazone patents, including the '777, '584, and '404 patents, as well as the method-of-use patents, for listing in the Orange Book. *End Payor*, 2015 WL 5610752, at *4; Am. Compl. ¶ 178.

Plaintiffs' entire claims focuses on the fact that Takeda's patent submissions to the FDA for the '584 and '404 patents noted they had both method-of-use and product claims. But the Orange Book listings for ACTOS do not say, and have never said, that the '584 and '404 patents have applicable "product" claims. Rather, these two patents are and have been listed only as "use" patents. The columns for "drug substance" and "drug product" claims are blank:

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Patent and Exclusivity Search Results from query on Appl No 021073 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021073	001	5965584	Jun 19, 2016			U - 753	
N021073	001	6150383	Jun 19, 2016			U - 418	
N021073	001	6150384	Jun 19, 2016			U - 419	
N021073	001	6166042	Jun 19, 2016			U - 414	
N021073	001	6166043	Jun 19, 2016			U - 415	
N021073	001	6172090	Jun 19, 2016			U - 416	
N021073	001	6211205	Jun 19, 2016			U - 410	
N021073	001	6271243	Jun 19, 2016			U - 411	
N021073	001	6303640	Aug 9, 2016			U - 425	
N021073	001	6329404	Jun 19, 2016			U - 753	

Ex. 8. The FDA has explained that like all patents submitted before 2003, the '584 and '404 patents "are flagged in the Orange Book listing for Actos only with respect to the method-of-use claims." Ex. 10 at 3. At the time, the FDA's "technological limitations" prevented the Orange Book from showing a "single patent . . . as claiming more than one aspect of a drug." *Id.* at 10. So a patent identified as having method-of-use claims was listed *only* as a method-of-use patent regardless of whether it was also identified as being a product patent. That Takeda told the FDA that the '584 and '404 patents have both method-of-use and product claims did not become public until Takeda filed its submissions publicly years after the fact, in 2010. Ex. 9, tabs A-B.

III. Generic Applications and Related Patent Litigation

In 2003, Actavis, Mylan, Ranbaxy, and Alphapharm (since acquired by Mylan) filed ANDAs seeking to market a generic version of ACTOS. *End Payor*, 2015 WL 5610752, at *5. Mylan and Alphapharm each filed a paragraph IV certification for the '777 patent; Actavis and Ranbaxy each filed a paragraph III certification. *Id.*

Actavis, Mylan, and Ranbaxy each filed paragraph IV certifications for the '584 and '404 patents and filed section viii carve-out requests regarding the other method-of-use patents, although there is no allegation that the FDA ever granted any of these section viii carve-out

requests. *Id.* As noted above, the Orange Book has always listed the '584 and '404 patents as having only method-of-use claims. And even Plaintiffs do not allege the generic applicants had notice at this time that Takeda had specified in its patent listing submissions to the FDA that these patents also had drug product claims. Critically, these generic companies nonetheless filed paragraph IV certifications, and not section viii carve-out requests, for the '584 and '404 patents.

Takeda sued all four companies in this District. Plaintiffs allege that Takeda filed these lawsuits "without regard to the merits" of the cases, but do not allege that the lawsuits were baseless, brought in bad faith, or sham litigation. *E.g.*, Am. Compl. ¶ 13.

Judge Cote, to whom the cases were assigned, tried Takeda's allegations of infringement of the '777 patent against Mylan and Alphapharm first. She found in favor of Takeda, ruled that the '777 patent was valid and infringed, found that Mylan and Alphapharm had engaged in "exceptional" misconduct and had filed their paragraph IV certifications in bad faith, and awarded Takeda over $16.8 million in attorney's fees. *Takeda*, 417 F. Supp. 2d at 399; *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 459 F. Supp. 2d 227, 230 (S.D.N.Y. 2006); *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 2007 WL 840368, at *1 (S.D.N.Y. Mar. 21, 2007). The Federal Circuit affirmed both the judgment of validity and the fee award; the Supreme Court denied certiorari in both cases. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 1295 (2008); *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 549 F.3d 1381 (Fed. Cir. 2008), *cert. denied*, 558 U.S. 821 (2009).

Back in the district court, the parties began additional discovery on the remaining patents. Takeda settled the litigations before trial. *End Payor*, 2015 WL 5610752, at *6.

ARGUMENT

I. Plaintiffs' Theory

Plaintiffs concede that Takeda was required by law to list the '584 and '404 patents in the

Orange Book for ACTOS. Am. Compl. ¶ 168 (describing Plaintiffs' view of "a lawfully accurate listing" of the '584 patent in the Orange Book for ACTOS); *id.* ¶ 174 (same for the '404 patent). In *End Payor*, this Court also recognized that "the '584 and '404 patents were properly listed in the Orange Book by Takeda as claiming methods of using ACTOS." *End Payor*, 2015 WL 5610752, at *21. Thus, unlike every other "improper Orange Book listing" case to date, there is no claim that the '584 and '404 patents should not have been listed in the Orange Book.

Rather, Plaintiffs (like *End Payor* plaintiffs) challenge Takeda's *description* to the FDA of the '584 and '404 patents as containing "product" claims. This is an unprecedented claim (except for the *End Payor* case). And as in the *End Payor* case, Plaintiffs' theory depends on a lengthy chain of assumptions:

1. That it was supposedly improper for Takeda to describe the '584 and '404 patents to the FDA as including product claims because such a patent infringement claim could not "reasonably be asserted" by Takeda against generic ACTOS products.

2. That generic applicants made paragraph IV certifications to these patents only because Takeda described them as having "product" claims. Otherwise, they would have sought FDA permission for section viii carve-outs to these patents.

3. That the FDA would have then granted the section viii carve-out requests by concluding that the safety or efficacy of the drug would not be affected by omitting from the drug label information on the use of combination therapies.

4. That generic versions of ACTOS would then have received earlier approval in the absence of the 30-month stay and 180-day exclusivity resulting from paragraph IV certifications.

5. That the generic companies would then launch their products at risk despite ongoing patent suits and the risk of treble damages for willful infringement.

6. That the generic products would not have infringed Takeda's patents.

As explained below, this lengthy chain of allegations piles implausible assumption on top of implausible assumption. And Plaintiffs' inability to plausibly allege any element of this chain of inference is fatal to their claim.

II. Each Link in Plaintiffs' Chain Is Implausible

A. Takeda's Patent Submissions Were Proper

To begin with, there was nothing improper in Takeda's patent submissions, including the description of the '584 and '404 patents as containing "product" claims. The Hatch-Waxman Act mandated that Takeda list any patent "with respect to which a claim of patent infringement *could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (emphasis added).[1] This "could reasonably be asserted" standard was clearly met with respect to the '584 and '404 patents.

Plaintiffs allege that the '584 and '404 patents' product claims for combination therapies could not reasonably be asserted against generic ACTOS products containing only pioglitazone. But this very argument was rejected by Judge Cote in the underlying patent litigation. Judge Cote specifically held that Takeda had a cognizable claim of induced infringement of these combination-use patents even if the generics sold a pioglitazone-only pill. *Takeda*, 2007 WL 2936208, at *5 (rejecting argument "that a generic drug manufacturer cannot induce infringement of combination-use patents").

Regardless of whether a pioglitazone-only pill would ultimately have been found to infringe the '584 and '404 patents, that a federal judge believed such a claim was cognizable and could prevail demonstrates that the patents' product claims "could reasonably be asserted" against a pioglitazone-only pill. In that circumstance, Takeda was not just permitted, but *obligated* under federal law to submit information on patents with such product claims to the FDA for inclusion in the Orange Book. *See Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at

[1] The "drug" referred to in § 355(b)(1) is the pioneer drug. Proposed generic drugs usually do not even exist at the time the patents are listed, after all. So the standard for Orange Book listing is whether the patent could be reasonably asserted if someone else sold an unlicensed version of the pioneer drug, *including administration according to its label directions*.

*3 (D. Del. Mar. 1, 2012) ("a pioneer drug manufacturer has the obligation to list those patents covering the pioneer drug in the Orange Book").

B. The Paragraph IV Certifications Had Nothing to Do with How Takeda Described Its Patents

Even if Plaintiffs were correct that Takeda should not have described the '584 and '404 patents as having "product" claims, their theory still makes no sense. The '584 and '404 patents contain some claims directed to methods of use and other claims directed to pharmaceutical products. Plaintiffs assume that if Takeda had described the patents to the FDA as just having "method of use" claims, then generic applicants would have (i) ignored the product claims in the patents, (ii) sought to rely only on section viii carve-outs, and (iii) not filed paragraph IV certifications. This assumption flies in the face of the indisputable facts. The reality is that the generic applicants' submission of paragraph IV certifications had nothing to do with how Takeda described its patents.

Regardless of the information Takeda submitted to the FDA, due to the FDA's practices at the time,[2] the Orange Book has always described the '584 and '404 patents only as "method-of-use" patents for ACTOS and never as "product" patents, as shown in Exhibit 8.[3] Thus, the Orange Book has always described the patents *exactly how Plaintiffs say they should have been described*. And the paragraph IV certifications at issue were not caused by Takeda's describing its patents to the FDA as having "product" claims because Takeda's description of its patents was not made public until years later, in 2010. Even Plaintiffs do not allege that Takeda's patent

[2] For patents listed before August 2003, "technological limitations" prevented the FDA Orange Book from showing a "single patent . . . as claiming more than one aspect of a drug." Ex. 10 at 10.

[3] Because the Orange Book is an official publication of the FDA, its contents are judicially noticeable. *See In re Thalomid & Revlimid Antitrust Litig.*, 2015 WL 9589217, at *13 n.11 (D.N.J. Oct. 29, 2015) (taking "judicial notice of the fact that [certain patents] are listed in the Orange Book as a matter of public record"); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) ("[t]he Court takes judicial notice of this fact, based on FDA public records" (citation omitted)).

submission letters were known to the generic applicants at the time the relevant paragraph IV certifications were submitted. According to the Amended Complaint and to the Hatch-Waxman system, the only patent information that the generic applicants relied on when they filed their ANDAs came from the Orange Book. *See*, e.g., *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 934 (N.D. Ill. 1995) ("'Congress intended that an ANDA applicant need consult only the Orange Book to determine the existence of an applicable patent claiming the listed drug or a use of the listed drug.'" (quoting FDA Citizen Petition Docket No. 94-P-144)).

Plaintiffs thus cannot plausibly allege that had Takeda submitted different patent information to the FDA there would have been no paragraph IV certifications. Mylan, Ranbaxy, and Actavis all filed paragraph IV certifications to the '584 and '404 patents without access to Takeda's patent submission letters, based solely on the Orange Book. Even if Takeda had not described the patents as "product" patents in its patent submission letters to the FDA, the Orange Book would have looked exactly the same and the generic applicants would have filed the same paragraph IV certifications. No factual allegation in the Amended Complaint is to the contrary.

Moreover, the reason that the generic companies filed paragraph IV certifications is that this is what the Hatch-Waxman system requires. No matter what the Orange Book says, the generic applicants could not avoid filing paragraph IV certifications to the non-method claims of the '584 and '404 patents. Generic applicants must provide a certification for each "*patent*" listed in the Orange Book. 21 C.F.R. § 314.94(a)(12) (emphasis added). Plaintiffs suppose that only part of the '584 and '404 patents should have been listed in the Orange Book, and the rest could have been ignored by the generic companies. But the FDA has rejected a claim-by-claim listing system by which innovator companies would list in the Orange Book only a subset of their listed patents' claims. *See* 68 Fed. Reg. 36,676, 36,685 (June 18, 2003) ("a claim-by-claim

declaration for all patents is not warranted"). There is no procedure permitting a generic applicant to ignore claims in a patent, regardless of whether the applicant thinks they are inapplicable. Nor is there a procedure for generic applicants to use section viii for patent claims that are not method claims.[4]

In short, no matter how Takeda had described its patents, the '584 and '404 patents would have been listed in the Orange Book just as they were, and the generic applicants would have filed paragraph IV certification to those patents just as they did.

C. Plaintiffs Cannot Allege that the FDA Would Have Approved Section viii Carve-Outs

Section viii permits a generic applicant to *request* the FDA's permission to omit from its label a specific use appearing in the pioneer drug's label (*e.g.*, using ACTOS with metformin). But the mere fact that a carve-out is requested does not mean that the FDA will approve it. The FDA approves a section viii request only if the labeling omission does not "render the proposed [generic] drug product less safe or effective than the [pioneer] drug." 21 C.F.R. § 314.127(a)(7). A section viii statement is improper also if the proposed labeling includes any part of the patent-protected uses described in the Orange Book: "[I]f the generic's proposed carve-out label overlaps *at all* with the brand's use code," then a section viii statement is improper, and the generic company must use a paragraph IV certification. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) (emphasis added). If the section viii carve-out is rejected, the generic applicant has to file a paragraph IV certification months, if not years, after when it would have otherwise filed the certification, delaying approval of its product.

Even if Plaintiffs could plausibly allege that the generics would have sought section viii

[4] In *End Payor*, the Court found it unnecessary to reach this issue because the complaint failed for other reasons. *See End Payor*, 2015 WL 5610752, at *21 n.18.

carve-outs instead of submitting paragraph IV certifications, Plaintiffs do not and cannot plausibly allege that the FDA would have granted those section viii requests. And if the FDA had ultimately denied the section viii requests, that denial would have only delayed approval of the relevant generic products.

All Plaintiffs allege is that the FDA has approved some labeling carve-out requests for other products. *See* Am. Compl. ¶¶ 103-107. But that tells us nothing about whether the FDA would have approved the hypothetical carve-out requests for generic ACTOS. Plaintiffs' "factual basis" that the FDA would have approved hypothetical section viii requests is no more persuasive than assuming that a patent will be held invalid just because sometimes other patents are held invalid. The FDA's decision for ACTOS would have been based on the specific medical evidence relating to ACTOS and the importance of combination therapies for the treatment of diabetes—something Plaintiffs pointedly fail to even address. Takeda specifically requested that the FDA refuse to approve generic labels that sought to carve out use of generic ACTOS in combination with metformin, on the ground that the carve-out would affect the drug's safety or efficacy. *See* FDA Citizen Petition Dkt. No. 2007-P-0294. The FDA has never ruled on Takeda's petition. Plaintiffs cannot premise antitrust claims on pure speculation over how the FDA would have decided such a complex scientific and legal issue. *Cf. End Payor*, 2015 WL 5610752, at *27 ("[A]ssumptions regarding success at trial are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise.").

D. Plaintiffs Do Not Allege Earlier Generic Approval

Count 1 fails for the additional reason that the Amended Complaint does not allege—despite repeated opportunities at amendment—that any particular generic company would have obtained earlier approval based on a section viii request. Without FDA approval, no company can lawfully market a drug. 21 U.S.C. § 355(a). If no generic applicant would have received

FDA approval but for the supposedly wrongful patent descriptions, nothing Takeda did could have caused any injury. *See In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004) ("failure to get needed regulatory approval may 'cut[] the causal chain and convert[] what might have been deemed antitrust injury in a free market into only a speculative exercise'" (alterations in original)).

Especially given the expense and burden of antitrust litigation on the courts and the parties, Plaintiffs should not be permitted to proceed without specific allegations of competitive harm, including which generic companies would have received earlier approval, when they would have received such approval, and why. *See, e.g.*, *4C Foods Corp. v. Package Automation Co.*, 2014 WL 6602535, at *5 (S.D.N.Y. Nov. 18, 2014) (refusing to "authorize a fishing expedition so [plaintiff] can try to fill in th[e] glaring hole in its pleading").

E. Plaintiffs' Do Not Allege that the Generic Applicants Would Have Launched Their Products at Risk of Treble Damages for Willful Infringement

Even if Plaintiffs could plausibly allege that Takeda's patent submissions were improper, that a different patent submission would have resulted in section viii requests rather than paragraph IV submissions, that those section viii requests would have been approved by the FDA, and that that would have somehow led to earlier generic approval, Plaintiffs' claims would still fail because Plaintiffs have not alleged that any generic company would have sold generic ACTOS in the face of patent suits from Takeda. Indeed, there is every reason to conclude that that would not have happened under any plausible scenario.

The '777 patent, which Judge Cote found valid and infringed, independently blocked entry of any generic version of ACTOS until it expired in 2011. *End Payor*, 2015 WL 5610752, at *22 ("generic entry was lawfully precluded until January 17, 2011, the date that the '777 patent expired"). Had generic companies come to market thereafter, they would have faced

patent suits from Takeda for induced infringement of its '584, '404, and numerous method-of-use patents. As the Court concluded in the *End Payor* case, Plaintiffs have not plausibly alleged (and could not plausibly allege) that Takeda would have refrained from asserting those patents especially given that Takeda did assert those patents against the generics: plaintiffs' assumption "that Takeda would not have pursued litigation based on the [Generic] Defendants' induced infringement of the method of use claims" was "particularly vexing because, as discussed above, there is no dispute that Takeda did pursue infringement inducement claims." *Id.* at *27.

Takeda's patent suits would have discouraged any company from marketing generic ACTOS product until the suits were resolved. Judge Cote, as noted above, had not only found the generic ACTOS products infringed the '777 patent, but also imposed $16.8 million in attorneys' fees on certain generic companies. Had the generic companies in Plaintiffs' hypothetical world sold generic ACTOS during the patent litigation, those sales of generic ACTOS would have been "at risk" because the generic would have faced the threat not only of attorneys' fees, but also of *treble* damages for willful infringement if it were found to infringe any one claim of any one of Takeda's numerous patents.

A company that sells product with full knowledge that it infringes a valid patent can be liable for treble damages for willful infringement. *See SRI Int'l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1464-65 (Fed. Cir. 1997). Because all pharmaceutical patents are listed in the Orange Book, the risk of willful-infringement damages is significant in this industry: "If a generic loses the infringement suit [after launching at risk], a court may award treble damages for willful infringement." Grace Lillian Wang, *Teva v. Eisai: What's the Real "Controversy"?*, 66 Food & Drug L.J. 631, 638 n.46 (2011). In the pharmaceutical industry, this could mean treble Takeda's lost profits on ACTOS, which would have been much larger than the generic

companies' own profits on generic ACTOS given the price difference between pioneer and generic drugs. Willful-infringement damages can thus be devastating for a generic company.[5] There is thus no basis to simply presume that a generic company would have sold the product any earlier even if it had received earlier approval. Plaintiffs cannot, thus, establish any anticompetitive injury to themselves.

F. Plaintiffs Cannot Allege that Generic ACTOS Products Would Not Infringe the '584 and '404 Patents

Plaintiffs are not entitled to claim as anticompetitive harm the inability to purchase a product that infringes a valid patent. *See, e.g.*, *Monarch Marking Sys., Inc. v. Duncan Parking Motor Maint. Co.*, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither [an antitrust counterclaimant] nor consumers have a right to the sale of labels which infringe Monarch's patents."), *vacated in part on other grounds*, 1988 WL 23830 (N.D. Ill. Mar. 8, 1988); *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907) (in an antitrust case, holding that "the public was not entitled to profit by competition among infringers"); *Hynix Semiconductor Inc. v. Rambus Inc.*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("an infringer [has] no legal right to be competing in the product market"); *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (dismissing antitrust claim alleging that defendants conspired to suppress importation of drugs whose importation was prohibited by federal law).

Thus, Plaintiffs cannot state a valid claim without asking the Court to assume that Takeda would have lost its patent infringement claims. To prevail on their theory, Plaintiffs would have to demonstrate that "the drug component claims of the '584 and '404 patents would not have

[5] For example, Teva and Sun paid *$2.15 billion* to settle damage claims arising from their alleged willful infringement by launching at risk a generic version of Protonix—a drug whose pre-generic-entry U.S. sales were of the same order of magnitude as ACTOS's pre-generic-entry U.S. sales. *After 10-Year Fight, Pfizer Wins Huge Patent Settlement*, N.Y. Bus. J., June 12, 2013, 2013 WLNR 14458758.

been infringed by the [generic] applications." *End Payor*, 2015 WL 5610752, at *21.

But Plaintiffs cannot plausibly allege that any generic manufacturer would have defeated Takeda's assertions of all those patents. As the Court previously concluded, "[a]t the time of the settlements at issue, no patent listed for ACTOS, including the '584 and '404 patents, had been found invalid or not infringed by a generic ANDA." *Id.* It is thus implausible to suggest that the generic products did not actually infringe at least one claim of one of Takeda's many patents.

Even if Plaintiffs tried to make factual allegations along these lines (which they have not), those allegations would be unduly speculative because "theories requir[ing] the Court to assume that Takeda's patent claims were invalid and the infringement actions against the Defendants would have failed . . . are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise." *Id.* at *27; *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 201-02 (E.D.N.Y. 2003) (allegations relying on "the hope that [the generic manufacturer] would have prevailed in its [patent] suit" were "too speculative" and "insufficient to state a claim under the antitrust laws"); *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015) ("allegations that the court would likely rule in favor of [the generic] is merely speculation"). Antitrust plaintiffs cannot reopen patent cases to seek a decision of complex noninfringement or invalidity issues simply because those issues were not decided the way Plaintiffs would have liked.

III. Plaintiffs Have Not Alleged Bad Faith

Finally, Count 1 fails for the independent reason that Plaintiffs have not plausibly alleged that Takeda acted in bad faith.

The listing of patents in the Orange Book is a legal requirement. 21 U.S.C. § 355(b)(1) (an applicant for an NDA "shall file" patent information for listing). "[A] pioneer drug manufacturer has the *obligation* to list those patents covering the pioneer drug in the Orange

Book." *Cephalon*, 2012 WL 682045, at *3 (emphasis added). When an antitrust claim is premised on a company's supposed failure to comply with its obligations imposed by law, the antitrust plaintiff must plead and prove bad faith. As the leading antitrust treatise explains, the bad faith requirement is necessary because "condemning conduct undertaken in a reasonable good faith effort to comply with [regulatory] policies would punish regulated firms for trying to act consistent with those policies." 1A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 246a, at 435 (4th ed. 2013).

Thus, antitrust claims alleging false Orange Book listings cannot be maintained without allegations of bad faith. *See, e.g.*, *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 964 (S.D. Ohio 2010) (granting motion to dismiss because "Sanofi's listing of the '265 patent in the Orange Book was not in bad faith"). Otherwise, the Hatch-Waxman system would put pharmaceutical companies in peril of violating the law for each pharmaceutical patent no matter what they do. Pioneer drug companies do not have discretion as to whether to list a patent. For each patent, pioneer drug companies are required to submit the patent if and only if "a claim of patent infringement could reasonably be asserted" for each potential generic product. 21 U.S.C. § 355(b)(1). Whatever the company decides, it can be held liable if a court later disagrees. *Id.* § 355(e)(4) (*failure* to list a patent when required to do so is grounds for FDA's withdrawal of NDA approval). If treble damages liability could follow for each good-faith effort to comply with the law, it not only would be unfair, but also would greatly discourage drug innovation.

Plaintiffs have made no effort to provide factual allegations of bad faith on Takeda's part. The Amended Complaint contains nothing more than conclusory allegations of bad faith. *See, e.g.*, Am. Compl. ¶ 171 ("When submitting the '584 Met Combo Patent information to the FDA, Takeda knew that the information was false and misleading."). Such conclusory allegations are

not well-pleaded facts. *See, e.g.*, *Wistron Corp. v. Phillips M. Adams & Assocs., LLC*, 2011 WL 4079231, at *5 (N.D. Cal. Sept. 12, 2011) ("Post-*Twombly* and *Iqbal*, courts have typically rejected conclusory allegations of knowledge."); *Yeftich v. Navistar, Inc.*, 722 F.3d 911, 916 (7th Cir. 2013) (holding that "bare assertions of the state of mind required for the claim—here, 'bad faith'—must be supported with subsidiary facts," and dismissing complaint because "plaintiffs have not gone beyond their conclusory state-of-mind allegations").

Moreover, as noted, Judge Cote denied a motion for judgment on the pleadings against Takeda's allegations of infringement of the composition claims, concluding that they had merit. *See Takeda*, 2007 WL 2936208, at *3-5. This should be dispositive of the question of whether Takeda acted in good faith. If a federal judge concludes that a reasonable claim could have been asserted, then certainly it could not have been bad faith for Takeda to reach the same conclusion.

IV. Leave to Amend Should Be Denied

Plaintiffs waited to file their complaint until after they had the benefit of the *End Payor* complaints, briefing on the motions to dismiss, and oral argument on those motions. They then were given the opportunity to amend their complaint in light of the Court's detailed opinion in the *End Payor* case. There is even more reason to deny leave to amend in this case than there was in the *End Payor* case. *See End Payor*, 2015 WL 5610752, at *29.

CONCLUSION

For the foregoing reasons, the Court should dismiss Count 1 with prejudice.

Respectfully submitted,

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